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SECTION 5: 510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 CFR807.92.

510(k) Number: K121571

5.1: Applicant Information

Date Prepared: April 18, 2012

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5.2: Device Information

Classification:	KNT
Trade Name:	TubeClear™
Common Name:	In Patient Nasogastric Tube Clearing System
Classification Name:	Tubes, Gastrointestinal and Accessories, 21 C.F.R. §876.5980

5.3: Predicate Device

The DeClogger, manufactured by Nova Design Technologies and cleared under 510(k) K905164 is the predicate device.

5.4: DEVICE DESCRIPTION

The Proposed Device, TubeClear™ is composed of a reusable Control Box and single use Clearing Stem. One Control Box Model, 101, is used to actuate all Clearing Stem models. Two Clearing Stem Models, NG-1036 and NG-1043, are available to accommodate different sizes of Tubes. The Operator manually inserts the Clearing Stem into the feeding or decompression tube (i.e., Tube) and directs the Clearing Stem's progression along the inside of the Tube. The Control Box Motor via electromechanical actuation creates a linear reciprocating motion. The linear reciprocating motion is transferred to the proximal end of the Clearing Stem which contains a Wire that also reciprocates. Because the Wire is continuous throughout the Clearing Stem, the reciprocating motion is further transferred to the distal Tip of the Wire. The motion at the Wire Tip mechanically acts on the occlusion and restores Tube patency.

Because the Control Box remains outside of the patient and it functions only to provide actuation to the Clearing Stem when the two are attached, the Clearing Stem is considered to be the primary element of TubeClear™. Accordingly, in this 510(k) application, the Clearing Stem is the focus of comparison with the Predicate Device, the DeClogger®.

5.5: INTENDED USE

The Proposed Device, TubeClear™, is substantially equivalent to the Predicate Device, the DeClogger®, in regards to intended use and therapeutic effect. The intended use for both Devices is to clear occlusions / clogs from feeding and decompression tubes (i.e., Tubes). The therapeutic effect for both Devices is restoring patency to the Tube and alleviating the need for Tube replacement.

Both the TubeClear™ Clearing Stem and the DeClogger® are disposable, single use devices. Both are prescription use, for sale by or on the order of a physician. Both are intended for use by Licensed Practical Nurses (LPNs), Registered Nurses (RNs), or Physicians. Both are intended for use at hospitals, in long term care facilities, and in homes (serviced by

licensed clinicians). Because both Devices enter a Tube that is within the Patient, neither device makes direct contact with the Patient. Because both Devices enter a Tube in the Patient's gastro-intestinal (GI) system, sterile conditions are not required for the intended purpose.

5.6: INDICATIONS FOR USE

TubeClear™ is indicated for use only and solely in clearing occlusions / clogs in nasogastric (NG) tubes (i.e., tubes that are placed through the nose and reside in the stomach) of adult patients. Clearing Stem Model NG-1036 is indicated for use in nasogastric tubes that are of size 10 – 14 French and have a length of 36 – 42 inches (91 - 108 cm). Clearing Stem Model NG-1043 is indicated for use in nasogastric tubes that are of size 10 – 18 French and have a length of 43 - 50 inches (109 – 127 cm).

The DeClogger® is indicated for use in clearing occlusions / clogs from percutaneous endoscopic gastrostomy tubes (PEG tubes) (i.e., tubes that are placed through the abdomen wall and rest in the stomach), gastrostomy tubes (G tubes) (i.e., tubes that are placed through the abdominal wall and rest in the stomach), and jejunostomy tubes (J tubes) (i.e., tubes that are placed through the abdomen wall and rest in the jejunum) of the patient.

The specific indications for use are different for TubeClear™ and the DeClogger®; however, the differences are not critical to the intended therapeutic use of the device, which is restoring patency to the Tube and alleviating the need for Tube replacement. The differences do not affect the safety and effectiveness of the Proposed Device, TubeClear™, when used as directed in the Operator's Manual.

5.7: TECHNOLOGICAL CHARACTERISTICS

TubeClear™ and the DeClogger®, have design features that are similar in terms of function and safety. Both have insertion guidance markings to measure depth that Device is inserted into the Tube. Both have a permanent design feature that limits the depth that the Device can be

inserted into the Tube. Both have multiple models differentiated by color to accommodate different sized Tubes and to aid in correct model selection. The TubeClear™ Wire Tip and the DeClogger® Screw-tip are rounded and flexible to minimize Tube damage and tissue injury if the error of over insertion were to occur. TubeClear™ and the DeClogger® have product dimensions to indicated tube ratios that are equivalent enabling effective and efficient passage within the Tube.

The Tips of both Devices physically interact with the occlusion material inside the Tube; thus, TubeClear™ and the DeClogger® have the same operating principle (i.e., both Devices mechanically act on occlusion to clear and restore Tube patency).

The primary technological difference between the Devices is that the TubeClear™ Clearing Stem Wire Tip actuation is created by transferred linear reciprocating motion from the Control Box Motor, while the DeClogger® Screw-tip actuation is created by the Operator manually rotating the DeClogger® Rod. Potential safety concerns raised by technological differences (i.e., tube movement, tube vibration causing discomfort and tube heating) were evaluated, and do not raise new safety questions. Potential effectiveness concerns due to technological differences were also evaluated, and do not raise new effectiveness questions.

5.8: NON-CLINICAL PERFORMANCE DATA

The Bench Testing was focused in four areas: Technical, Efficacy, Safety, and Electrical Safety. Technical testing included verification of product specifications, reliability, transportation vibration, shelf life, and firmware verification and validation. Efficacy testing included usability and effectiveness. Safety testing included the effect of the Devices on feeding and decompression tubes (i.e., Tubes) in terms of Tube damage, Tube heating and Tube movement / dislodgement. Safety testing also included magnetic field testing. Electromagnetic Compatibility (EMC) and Electrical Safety Tests were performed by Intertek Group, Inc. (Boxborough, MA).

EMC testing was conducted to the IEC standards 60601-1-2:2001 +A1:2004.

5.8.1: Technical Testing

Verification confirmed that the Clearing Stem and Control Box met product specifications passing all acceptance criteria. Evaluation of the reliability of the Control Box passed testing equivalent to one year of operation. Transportation vibration testing successfully passed acceptance criteria for US highway truck. Shelf life was tested via accelerated life testing and passed 6 month storage. Additional testing for longer shelf life is ongoing. Firmware validation was tested to a 'moderate' level and passed all the acceptance criteria.

5.8.2: Efficacy Testing

Usability and retainability testing by end users passed all acceptance criteria. Evaluation of effectiveness during simulated use was performed for both TubeClear™ and the DeClogger®. They were found to be of equivalent effectiveness.

5.8.3: Safety Testing

Safety testing in terms of Tube damage (e.g., scratches, nicks, tears, abrasions, punctures) to the inner tube surface after device operation was found to be equivalent for the Proposed and Predicate Devices. Heating during device operation was negligible, (less than the resolution of the test equipment); thus the Devices have equivalent safety in terms of heating. Tube movement was measured and found to be of the same magnitude, thus equivalent for both Devices. A caution was added to the Operator's Manual to account for discomfort that may occur during insertion of TubeClear™ into a Tube. The magnetic field was tested around the Control Box and Clearing Stem. Magnetic field strength passed the acceptance criteria for safe operation under normal use conditions.

5.8.4: Electrical Safety Testing

TubeClear was tested to eight (8) electrical safety standards and met all requirements. The standards are as follows:
(1) UL 60601-1 UL Standard for Safety Medical electrical Equipment, Part 1: General Requirements for Safety. Ed: 1 Rev:2006/4/26;
(2) CSA C22.2#60601-1 Medical Electrical Equipment – Part 1 – General Requirements for Basic Safety and Essential Performance. Ed: 2. Issue: 2003/04/25;
(3) IEC 60601-1-2, Medical Electrical Equipment – Part 1-2: General Requirements for Safety - Collateral standard: Electromagnetic Compatibility – Req. Ed: 2 Issue: 2001/09/30;
(4) IEC 60601-1 Medical Electrical Equipment – Part 1: General Requirements for Safety; (Amd. 1-1991) (CENELEC EN 60601-1: 1990) (Amd. 2-1995) Ed. 2 Issue 1998/12/01;
(5) CENELEC EN60601-1, Medical Electrical Equipment. Part 1: General Requirements for Safety Incorporates Corrigendum July 1994; Includes Amd. A1: 1993; A11: 1993; A12: 1993; A2: 1995;
(6) IEC 60601-1-4, Medical Electrical Equipment – Part 1-4: General Requirements for Safety – Collateral Standard: Programmable Electrical Medical Equipment: Ed:1.1 Issue: 2000/04/01;
(7) IEC 60601-1-6, Medical Electrical Equipment – Part 1-6: General Requirements for Safety – Collateral Standard: Usability. Ed: 2 Issue: 2006-12; and
(8) ISO 14971:2007, Medical Devices – Application of Risk Management to Medical Devices.

5.9: CLINICAL PERFORMANCE DATA

No clinical data was collected; therefore, no clinical data is presented in this submission.

5.10: CONCLUSIONS

The scientific data demonstrates that the Proposed Device, TubeClear™ is substantially equivalent to the Predicate Device, the DeClogger®. TubeClear™ and the DeClogger® (i.e., the Devices) have the same intended use and share similar design features. The Devices have some differences in technological characteristics; however, those differences have been evaluated and do not raise new questions about safety and effectiveness. The 510(k) Substantial Equivalence Decision Making Process Flow Chart was used by Actuated Medical, Inc. to determine Substantial Equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUN 13 2012

Actuated Medical, Inc.
% Mr. William Sammons
Sr. Project Engineer - Medical Devices
Intertek Testing Services NA, Inc.
2307 East Aurora Rd. Unit B7
TWINSBURG OH 44087

Re: K121571
Trade/Device Name: TubeClear™ Model 101
Regulation Number: 21 CFR§ 876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: II
Product Code: KNT
Dated: May 24, 2012
Received: May 29, 2012

Dear Mr. Sammons:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K121571

SECTION 4: FDA 510(K) INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K121571

Device Name: TubeClear™ Model 101

Indications for Use Statement

TubeClear™ is indicated for use only and solely in clearing occlusions / clogs in nasogastric (NG) tubes (i.e., tubes that are placed through the nose and reside in the stomach) of adult patients. Clearing Stem Model NG-1036 is indicated for use in nasogastric tubes that are of size 10 – 14 French and have a length of 36 – 42 inches (91 - 108 cm). Clearing Stem Model NG-1043 is indicated for use in nasogastric tubes that are of size 10 – 18 French and have a length of 43 - 50 inches (109 – 127 cm).

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

13 JUNE 2012

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K121571